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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/714,692	11/16/00	LEE	D6233CIP

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HM12/0406

EXAMINER
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TON, T

ART UNIT	PAPER NUMBER
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1632

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DATE MAILED:

04/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/714,692

Applicant(s)

LEE ET AL.

Examiner

Thaian N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-27 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to a transgenic mouse with a disruption in at least one allele of the corticotropin releasing factor 2 (CRFR2), and a method of screening a compound for anxiety modulating activity and administering to the transgenic mouse, classified in class 800, subclass 18, for example.
- II. Claim 9 drawn to a method of screening for a compound for depression-modulating activity and testing its effects in a transgenic mouse, classified in class 800, subclass 3, for example.
- III. Claim 10, drawn to a method of screening for compounds which control blood pressure and testing its effects in a transgenic mouse, classified in class 800, subclass 3, for example.
- IV. Claim 11, drawn to a method of screening for compounds which affect angiogenesis and testing its effects in a transgenic mouse, classified in class 800, subclass 3, subclass.
- V. Claims 12-13, drawn to a method of screening for a compound for effects on the response to the hypothalamic-pituitary-adrenal axis to stress and testing its effects in a transgenic mouse, classified in class 800, subclass 3, for example.
- VI. Claims 14-15, drawn to a method of determining the effects of CRFR2 on a second protein and testing its effects in a transgenic mouse, classified in class 800, subclass 3, for example.
- VII. Claims 16-19, drawn to a gene therapy to stimulate increased angiogenesis, classified in class 514, subclass 44, for example.
- VIII. Claims 20-23, drawn to protein therapy to inhibit angiogenesis, classified in class 514, subclass 2, for example .
- IX. Claims 24-27, drawn to protein therapy to stimulate hair growth, classified in class 514, subclass 2, for example.

The inventions are distinct, each from the other because of the following reasons:

Invention I is distinct from Inventions II-IX, as the transgenic mouse in Invention I can be used in methods that are distinct from the methods in Inventions II-IX. For example, the transgenic mouse in Invention I can be used as a bioreactor for proteins *in vivo*.

Inventions II-VI are distinct, each from each other, because each method in each invention requires an independent search status. Each of the Inventions II-VI require an independent search status because the testing and comparing in each method involves different parameters to evaluate the disclosed conditions (depression-modulating activity, blood pressure, angiogenesis, effects of CRFR2 on a second protein).

Inventions II-VI are distinct from Inventions VII-IX because the methods in the Inventions II-VI are directed towards testing and comparing the effects on a transgenic mouse, whereas the Inventions VII-IX are directed towards therapy. Thus the differences between Inventions II-VI and VII-IX are further underscored by their divergent classification and independent search status.

Invention VII is distinct from Inventions VIII-IX because the nucleotides in Invention VII are materially, structurally and functionally different from the peptides in Inventions VIII-IX. Additionally, nucleotides and peptides can be used by materially different methods. Nucleotides can be used as detection probes and polypeptides can be used for antigen presenting cell priming, for example. The differences between

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Invention VII and Inventions VIII-IX are further underscored by their divergent classification and independent search status.

Invention VIII is distinct from Invention IX because different parameters are required in evaluating the inventions; Invention VIII is directed towards inhibiting angiogenesis, whereas Invention IX is directed towards stimulation of hair growth. The differences between Inventions VIII and IX are further underscored by their independent search status.

The inventions above have acquired a separate status in the art as a separate subject for inventive effort and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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A telephone call was made to Dr. Benjamin Aaron Adler on April 5, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

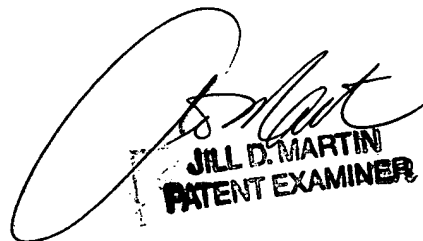
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. Should the examiner be unavailable, inquiries should be directed to Karen Hauda, Supervisory Primary Examiner of Art Unit 1632, at (703) 6608. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

TNT

Thaian N. Ton  
Patent Examiner  
Group 1632



JILL D. MARTIN  
PATENT EXAMINER